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Original Research Article

Alfuzosin versus tamsulosin for symptomatic benign prostatic hyperplasia: a prospective comparative study

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ABSTRACT

Background: Benign prostatic hyperplasia (BPH) is a common cause of lower urinary tract symptoms (LUTS) in aging men. Alpha-1 adrenergic receptor antagonists are recommended as first-line pharmacological therapy. This study compared the efficacy and safety of alfuzosin and tamsulosin in men with symptomatic BPH.
Methods: In this prospective, open-label, comparative study, 60 men with symptomatic BPH were allocated to receive either alfuzosin 10 mg once daily (n=30) or tamsulosin 0.4 mg once daily (n=30) for 12 weeks. International Prostate Symptom Score (IPSS), maximum urinary flow rate (Qmax), and post-void residual urine volume (PVRU) were assessed at baseline, 4 weeks, and 12 weeks. Adverse events were recorded throughout the study.
Results: Baseline characteristics were comparable between groups. Both treatments produced significant improvement in IPSS, Qmax, and PVRU from baseline to 12 weeks (all $p<0.001$). At 12 weeks, mean IPSS was lower in the alfuzosin group than in the tamsulosin group (6.30±2.02 vs. 7.37±2.17; $p=0.050$). Mean Qmax increased from 6.03±1.81 to 23.33±3.79 ml/s with alfuzosin and from 6.30±1.73 to 21.60±4.10 ml/s with tamsulosin ($p=0.090$). Mean PVRU decreased from 85.30±28.51 to 11.40±6.08 ml and from 73.90±45.51 to 14.83±11.93 ml, respectively ($p=0.160$). Both medications were well tolerated, and no serious adverse events occurred.
Conclusions: Both alfuzosin and tamsulosin significantly improved LUTS, urinary flow rate, and bladder emptying in men with symptomatic BPH. Their efficacy and safety profiles were broadly comparable.

Keywords: Alfuzosin, Benign prostatic hyperplasia, IPSS, Lower urinary tract symptoms, Tamsulosin, Uroflowmetry

INTRODUCTION

Benign prostatic hyperplasia (BPH) is one of the most common urological disorders affecting ageing men and a major cause of lower urinary tract symptoms (LUTS) worldwide. The prevalence of histological BPH increases progressively with age, affecting approximately 50% of men by the sixth decade and up to 80-90% by the ninth decade of life.[1-3] As life expectancy continues to increase globally, the burden of BPH and its associated healthcare utilization is expected to rise further.[1,2] Patients commonly present with urinary frequency, urgency, nocturia, hesitancy, intermittency, weak urinary stream and incomplete bladder emptying, symptoms that substantially impair quality of life and may progress to acute urinary retention, recurrent urinary tract infections, bladder calculi, and renal dysfunction if left untreated.[2,3]

The pathophysiology of BPH-associated LUTS is multifactorial and involves both static and dynamic components of bladder outlet obstruction. The static component results from enlargement of the prostate gland, whereas the dynamic component is mediated by increased

smooth muscle tone within the prostate, bladder neck, and prostatic urethra. α1-Adrenergic receptors play a pivotal role in regulating this smooth muscle tone and therefore represent an important pharmacological target in the medical management of symptomatic BPH.[4,5]

Current international guidelines recommend α1-adrenergic receptor antagonists as first-line pharmacological therapy for men with moderate-to-severe LUTS secondary to BPH because of their rapid onset of action, favourable safety profile, and proven efficacy in improving urinary symptoms and urinary flow.[6,7] Among the available agents, alfuzosin and tamsulosin remain among the most frequently prescribed α1-adrenergic receptor antagonists in routine clinical practice**.** Alfuzosin is considered functionally uroselective because of its preferential distribution within prostatic tissue, whereas tamsulosin demonstrates greater selectivity for the α1A-adrenoceptor subtype predominantly expressed in prostatic smooth muscle. These pharmacological differences may influence therapeutic efficacy, cardiovascular tolerability, ejaculatory adverse effects, and overall treatment adherence.[4,5] Although both medications have demonstrated effectiveness in improving urinary symptoms and urinary flow parameters, comparative studies have reported inconsistent findings regarding symptom improvement and tolerability.[8-11] Although several comparative studies have evaluated these agents, variability in efficacy and tolerability reported across studies highlights the need for further comparative evaluation in routine clinical practice. Given the widespread use of both medications as first-line therapy, further comparative evaluation may help clinicians individualize treatment according to efficacy and safety profiles.

Therefore, the present prospective comparative study was undertaken to evaluate and compare the efficacy and safety of alfuzosin 10 mg once daily and tamsulosin 0.4 mg once daily in men with symptomatic benign prostatic hyperplasia. Efficacy was assessed using changes in the IPSS, maximum urinary flow rate (Qmax), and post-void residual urine volume (PVRU), while safety was evaluated by monitoring treatment-emergent adverse events.

METHODS

Study design and setting

This prospective, open-label, comparative study was conducted between February 2020 and July 2021 in the Departments of Pharmacology and Urology, Patna Medical College and Hospital, Patna, Bihar, India, after obtaining approval from the Institutional Ethics Committee.

Study participants

Male patients aged ≥45 years with a clinical diagnosis of symptomatic benign prostatic hyperplasia (BPH) were screened for eligibility. Patients with an International Prostate Symptom Score (IPSS) >4, prostate-specific antigen (PSA) <10 ng/mL, and a maximum urinary flow rate (Qmax) <12 ml/s but ≥2 ml/s for a voided volume >120 ml were included.

Patients with suspected carcinoma of the prostate, PSA >10 ng/ml, neurogenic bladder, upper motor neuron lesions, urethral stricture, urinary bladder stones, previous prostate surgery, prior treatment for BPH, known hypersensitivity to α1-adrenoceptor antagonists, or urinary tract infection were excluded.

Treatment allocation

Eligible patients were allocated in a 1:1 ratio to one of two treatment groups using a pre-specified allocation schedule based on outpatient registration numbers. Group A received alfuzosin 10 mg orally once daily. Group T received tamsulosin 0.4 mg orally once daily. A total of 60 patients were enrolled, with 30 patients assigned to each treatment group.

Clinical assessment

A detailed medical history and physical examination were performed at baseline. Digital rectal examination was conducted by the consulting urologist to assess prostate size and consistency. Baseline investigations included serum PSA, random blood glucose, routine urine examination, ultrasonography of the prostate, post-void residual urine (PVRU) measurement, and uroflowmetry. Symptom severity was assessed using the International Prostate Symptom Score (IPSS). Patients completed the IPSS questionnaire after receiving standardized instructions from the investigators.

Follow-up and outcome measures

Patients were followed at 4 weeks and 12 weeks after initiation of therapy. The primary efficacy outcomes were: Change in IPSS, Change in maximum urinary flow rate (Qmax) measured by uroflowmetry. Secondary efficacy outcomes included change in post-void residual urine (PVRU). Safety was assessed through monitoring and documentation of adverse events throughout the study period.

Statistical analysis

Data were analysed using Epi Info™ version 7.1 (Centres for Disease Control and Prevention, Atlanta, GA, USA). Continuous variables are presented as mean ± standard deviation (SD), while categorical variables are presented as frequencies and percentages. Between-group comparisons were performed using the independent-samples t-test. Within-group changes from baseline to follow-up visits were analysed using the paired t-test. A two-sided p value <0.05 was considered statistically significant.

RESULTS

Baseline characteristics

A total of 60 patients with symptomatic benign prostatic hyperplasia were enrolled and completed the study, with 30 patients each in the alfuzosin and tamsulosin groups. Baseline demographic and clinical characteristics were comparable between the two groups (Table 1). The mean age was 66.6±8.4 years in the alfuzosin group and 65.8±8.6 years in the tamsulosin group. Baseline IPSS, Qmax, PVRU, PSA, prostate volume, and digital rectal examination findings did not differ significantly between groups (all p>0.05).

Table 1: Baseline demographic and clinical characteristics of study participants.

Variables	Alfuzosin (n=30), Mean±SD	Tamsulosin (n=30), Mean±SD	P value
Age (years)	66.6±8.4	65.8±8.6	-
IPSS score	17.90±6.38	17.23±7.56	0.713
PSA (ng/ml)	3.32±1.98	4.06±2.38	-
PVRU (ml)	85.30±28.51	73.90±45.51	0.250
Prostate volume (ml)	57.27±20.05	42.13±21.34	-
DRE score	2.40±0.72	2.03±0.72	-
Qmax (ml/s)	6.03±1.81	6.30±1.73	0.561

Efficacy outcomes

IPSS

Both treatments produced significant improvement in IPSS from baseline to 12 weeks (Table 2). At one-month, mean IPSS was numerically lower in the tamsulosin group than in the alfuzosin group (9.6±3.6 vs. 11.6±5.0), although the difference was not statistically significant (p=0.083). At 12 weeks, the alfuzosin group demonstrated a lower mean IPSS than the tamsulosin group (6.3±2.0 vs. 7.37±2.17), reaching borderline statistical significance (p=0.05).

Maximum urinary flow rate (Qmax)

Both groups showed significant improvement in urinary flow rate during follow-up. Mean Qmax increased from 6.03±1.8 to 23.33±3.79 mL/s in the alfuzosin group and from 6.30±1.7 to 21.60±4.09 mL/s in the tamsulosin group. Although Qmax values were numerically higher in the alfuzosin group at 12 weeks, the between-group difference was not statistically significant (p=0.09).

Post-void residual urine volume (PVRU)

Both treatments significantly reduced post-void residual urine volume from baseline. Mean PVRU decreased from 85.3±28.5 ml to 11.4±6.1 ml in the alfuzosin group and from 73.9±45.5 ml to 14.8±11.9 ml in the tamsulosin group. No statistically significant differences were observed between groups at either follow-up visit (p>0.05).

Within-group analysis

Within-group analysis demonstrated significant improvement from baseline in IPSS, Qmax, and PVRU in both treatment groups at 12 weeks (all p<0.001).

Safety outcomes

Both medications were well tolerated, and no serious adverse events or treatment discontinuations were reported. Dizziness was the most frequently reported adverse event, occurring in three patients in the alfuzosin group and two patients in the tamsulosin group. Constipation and fatigue were reported only in the alfuzosin group, while headache occurred in two patients in each group. All adverse events were mild and self-limiting (Table 4).

Table 2: Comparison of IPSS, PVRU and Qmax between the alfuzosin and tamsulosin groups during follow-up.

Outcomes	Time point	Alfuzosin (n=30), Mean±SD	Tamsulosin (n=30), Mean±SD	P value
IPSS	Baseline	17.90±6.38	17.23±7.56	0.713
	1 month	11.60±5.05	9.60±3.61	0.083
	3 months	6.30±2.02	7.37±2.17	0.050
PVRU (ml)	Baseline	85.30±28.51	73.90±45.51	0.250
	1 month	33.63±17.84	32.00±23.40	0.762
	3 months	11.40±6.08	14.83±11.93	0.160
Qmax (ml/s)	Baseline	6.03±1.81	6.30±1.73	0.561
	1 month	14.67±3.52	15.53±2.69	0.288
	3 months	23.33±3.79	21.60±4.10	0.090

Table 3: Magnitude of improvement in efficacy outcomes from baseline to 3 months.

Outcomes	Alfuzosin mean change (95% CI)	Tamsulosin mean change (95% CI)	Between-group difference	P value
IPSS	-11.60 (-14.0 to -9.1)	-9.90 (-12.7 to -6.9)	-1.70	0.050
PVRU (ml)	-73.90 (-84.5 to -63.2)	-59.10 (-76.2 to -41.8)	-14.80	0.160
Qmax (ml/s)	+17.30 (15.7 to 18.8)	+15.30 (13.5 to 16.9)	+2.00	0.090

Table 4: Treatment-emergent adverse events reported during the study period.

Adverse events	Alfuzosin (n=30), (%)	Tamsulosin (n=30), (%)
Dizziness	3 (10.0)	2 (6.7)
Constipation	2 (6.7)	0
Headache	2 (6.7)	2 (6.7)
Fatigue	2 (6.7)	0
Any adverse event	9 (30.0)	4 (13.3)

DISCUSSION

The present prospective comparative study demonstrated that both alfuzosin and tamsulosin produced clinically and statistically significant improvements in symptom severity, urinary flow rate, and post-void residual urine volume over 12 weeks of therapy. No participant was lost to follow-up, and both medications were generally well tolerated. Although tamsulosin demonstrated numerically greater improvement during the first month of treatment, alfuzosin showed numerically greater improvement at study completion; however, these differences did not establish clear clinical superiority of either treatment.

Baseline demographic and clinical characteristics were comparable between treatment groups, permitting meaningful assessment of therapeutic outcomes. The mean age of participants was approximately 66 years in both groups, which is consistent with the established epidemiology of BPH reported by Berry et al and Lepor et al, who demonstrated a progressive increase in the prevalence of histological and clinical BPH with advancing age.[1,2]

Symptom improvement, as measured by the International Prostate Symptom Score (IPSS), was substantial in both treatment groups. At one month, the reduction in IPSS was numerically greater in the tamsulosin group, whereas at three months the alfuzosin group demonstrated a lower mean IPSS score. Similar findings have been reported by Manjunatha et al, who observed greater long-term reduction in symptom scores among patients receiving alfuzosin compared with tamsulosin.[7] Buzelin et al also reported greater improvement in IPSS among patients treated with alfuzosin, whereas Karadağ et al demonstrated comparable symptomatic benefit between the two drugs in a randomized double-blind study.[8,9] The differences observed among studies may be attributable to variations in baseline symptom severity, patient characteristics, treatment duration, and outcome assessment methods.

Both treatment groups demonstrated marked improvement in urinary flow parameters. Mean Qmax increased significantly from baseline in both groups, reflecting effective relief of the dynamic component of bladder outlet obstruction. Although alfuzosin achieved numerically higher Qmax values at 12 weeks, the between-group difference was not statistically significant. These findings are consistent with those reported by Karadağ et al., who found comparable improvement in urinary flow rates among patients receiving alfuzosin and tamsulosin.[9] Furthermore, the systematic review and meta-analysis by Fusco et al confirmed that α1-adrenergic receptor antagonists significantly improve urodynamic parameters in men with LUTS secondary to BPH, although clinically meaningful differences between individual agents remain limited.[11]

Post-void residual urine volume also decreased significantly in both groups. Improvement was evident at the first follow-up visit and continued throughout the study period. The magnitude of reduction was comparable between treatments, supporting the effectiveness of both drugs in improving bladder emptying. These findings are in agreement with pooled analyses and comparative studies evaluating α1-blockers in symptomatic BPH.[12]

No significant changes were observed in prostate-specific antigen levels or prostate volume during the study period. This finding is biologically plausible because α1-adrenergic receptor antagonists primarily reduce smooth muscle tone within the prostate and bladder neck without directly affecting prostatic growth. Previous studies have similarly demonstrated symptomatic improvement despite minimal changes in prostate volume or PSA levels during treatment.[3,13]

Both medications exhibited favourable safety profiles. Adverse events were mild, transient, and did not result in treatment discontinuation. Dizziness was the most frequently reported adverse event in both groups. Numerically, adverse events were more common in the alfuzosin group, which may be related to its lower receptor subtype selectivity. Tamsulosin exhibits greater affinity for the α1A-adrenoceptor subtype predominantly expressed in prostatic tissue and therefore generally produces fewer vascular adverse effects.[4,14] Nevertheless, no serious adverse events or treatment discontinuations occurred in either group, and the overall incidence of

adverse events was low and comparable to that reported in previous studies and systematic reviews.[7,11,13]

Strengths of the present study include complete follow-up of all enrolled participants, comparable baseline characteristics between treatment groups, and serial assessment of clinically relevant outcomes including IPSS, Qmax, and PVRU. These factors enhance the internal validity of the findings and permit meaningful comparison of treatment effects.

However, several limitations should be considered. The study was conducted at a single tertiary care centre and included a relatively small sample size, which may limit the generalizability of the findings. The open-label design may have introduced performance and assessment bias. The duration of follow-up was limited to 12 weeks and therefore may not fully capture long-term efficacy, adherence, or safety outcomes. Future multicentre studies with larger sample sizes, rigorous randomization procedures and longer follow-up are warranted to confirm these findings.

CONCLUSION

Both alfuzosin and tamsulosin were effective in improving lower urinary tract symptoms, urinary flow rate, and post-void residual urine volume in men with symptomatic benign prostatic hyperplasia. The overall efficacy and safety profiles of the two agents were comparable, supporting their continued use as first-line medical therapy for patients with BPH-associated LUTS.

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